REMARKS

This amendment is responsive to the Office Action mailed February 25, 2004. Original claims 1-32 are under examination in the present action. All pending claims stand rejected. In addition, claim 23 is objected to on separate grounds. No claim is allowed.

1. The Examiner has made the restriction requirement as set forth in Office Action mailed May 7, 2003 final. Applicants respectfully request reconsideration thereof. As stated in the Applicants' Reply submitted November 7, 2003, the invention of the instant application is not "a chemical structure or unlimited pharmaceutical composition, but rather is *a method* of decreasing body weight." (emphasis added). Claims 2-32 which are dependent upon claim 1, are all directed to the use of particular, *known* somatostatin agonists that may be used to practice the novel method of the instant application. The Examiner's statement that "[a]s the somatostatins have different structures...[an as such].. the function [sic]...vary" indicates a lack of appreciation of the present invention. As indicated on page 8 of the specification, the analogs of claim 23 are known somatostatin agonists disclosed in the list of publications incorporated by reference found at page 9, line 4 to page 10, line 27. The Examiner's request that Applicants state on the record that a particular reference anticipates all of the structures contained in claim 23 is unnecessary. Since all of

the compounds share a similar function which is known, i.e., ability to act as an agonist of somatostatin, and since the claims of the instant application are all directed to use of a somatostatin agonist, unity exists. Applicants, therefore, respectfully request reconsideration of the finality of the restriction requirement.

3. Claim 23 is objected to as not complying with the requirements for patent applications containing nucleotide and/or amino acid sequences. In response thereto, claim 23 has been amended to insert the corresponding sequence identifier for those peptides subject to said requirements. In particular, "(SEQ ID NO:1)" has been inserted after the 64th peptide of claim 23, "(SEQ ID NO:2)" and after the 66th peptide of claim 23 and "(SEQ ID NO:3)" was inserted after the 92nd peptide of claim 23. Applicants submit that no other peptide listed in claim 23 requires an identifier since all other peptides contain at least one D-amino acid.

4. Claims 1-32 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for "failing to particularly point out and distinctly claim the subject matter which the applicant [sic] regards as the invention" since the claims recite "a method to decrease body weight in a patient." As discussed MPEP §2171, there are two separate requirements set forth in the second paragraph of 35 U.S.C. 112:

(A) the claims must set forth the subject matter that the applicants regard as their invention; and

(B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

The first requirement is a subjective one because it is dependent on what the applicants for a patent regard as their invention. The second requirement is an objective one because it is not dependent on the views of applicant or any particular individual, but is evaluated in the context of whether the claim is definite - i.e., whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art. If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph. Claim 1 is directed to the use of a therapeutically effective amount of somatostatin or its agonist to decrease body weight in a patient. Applicants submit that one skilled in the art can easily understand that the scope of the present application is use a particular compound, i.e. somatostatin or its agonist, as defined at page 7, line 30, to page 8, line 27, to decrease the weight of a patient as discussed on page 2. Applicants respectfully submit that no aspect of the relevant definitions is indefinite to the extent that one skilled

in the art could not determine what compounds are used to treat what condition.

The Examiner raises several questions in support of her rejection of claims 1 - 32 under 35 U.S.C. 112, second paragraph, such as how much weight can be lost by a patient subjected to the claimed method, what type of patient is best treated by the method and how long the method must be practiced before the desired weight loss is achieved[1]. Applicants submit that none of these questions are directed to meaning of a particular word or phrase, but are more appropriate to inquiry as to the enablement of the claimed method. As stated in MPEP §2173.04, "[i]f the claim is too broad because it is not supported by the original description or by an enabling disclosure, a rejection under 35 U.S.C. 1212, first paragraph, would be appropriate." If the Examiner is of the opinion that the answers to her questions provides omitted matter disclosed to be essential to the invention as described in the specification, a rejection under 35 U.S.C. 112, first paragraph, is appropriate. "Breadth of a claim is not to be equated with indefiniteness." *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971).

For the reasons given above, pending claims 1 - 32 are clear and definite to one skilled in the art. Applicants submit

[1] The Applicants in no way limit their present method of weight loss to any particular amount, body type or time limit. No where in the specification is it indicated that such parameters are necessary to practice the claimed method.

that the rejection of claims 1 - 32 under 35 U.S.C. 112, second paragraph, for indefiniteness must be withdrawn.

Claims 12-22 have additionally been rejected under 35 U.S.C. 112, second paragraph, for employing an improper sentence structure. In particular, the Examiner has rejected said claims for use of "an" and not "a" before the phrase "non-insulin-dependent diabetic human." Applicants concur with the Examiner on this point and have amended claims 12-22 accordingly.

5. The Examiner has advised the Applicants of their obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102 (f) or (g) or prior art under 35 U.S.C. 103(a). Applicants advise that the instant application is application filed under the provisions 35 U.S.C. 371 and is based upon international patent application PCT/EP98/02999 which claims priority from U.S. Patent Application Serial No. 08/854,941. It should be noted that the present application claims subject matter that was fully disclosed in the '971 application. The '971 application has the same inventorship and ownership as the instant application.

6. Claims 1, 4, 6, 8, 10, 11 and 32 are rejected under 35 U.S.C. 103 as being unpatentable over WO 96/35950 in the name of Dunmore *et al.* (hereinafter referred to as "Dunmore") in view of Huang, H.-J., Suppl. Hypertension, (1992) 19(1):I101-9

(hereinafter referred to as "Huang"). The Examiner at page 4 of the pending Office Action states that Dunmore teaches that somatostatin type-5 receptor agonists[2] are effective in reducing hyperamylinemia. Huang, which is referred to by Dunmore, is cited for the proposition that "hyperamylinemia is not simply a passive partner to hyperinsulinemia, but rather it acts as a causative mechanism of insulin resistance and associate metabolic derangements including obesity." In light of this teaching, the Examiner argues that "one of skill in the art would be motivated to use somatostatin type-5 receptor [sic] in the treatment of obesity." As such, the Examiner concludes that that the claimed invention was within the skill of the art and is thus *prima facie* obvious.

Applicants respectfully bring to the Examiner's attention that she has misquoted Huang. The relevant passage from Huang cited by the Examiner is:

> *The present studies indicate that hyperamylinemia is not simply a passive partner to hyperinsulinemia. Rather, it* ***could*** *act as a causative mechanism of insulin resistance and associated metabolic derangements, including obesity.*

Applicants respectfully request correction.

Applicants respectfully disagree with the rejection of claims 1, 4, 6, 8, 10, 11 and 32 under 35 U.S.C. 103(a) under

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[2] The Examiner notes that Dunmore discloses use of a somatostatin agonist, i.e., H-Cys-Phe-Phe-D-Trp-Lys-Thr-Phe-Cys-NH_2, which is claimed in the instant application as being effective in use to decrease weight according to the method of the instant application.

Dunmore, Huang or a combination thereof. Applicants submit that the Examiner's finding is based upon impermissible hindsight. Neither Dunmore nor Huang suggest that hyperamylinemia or hyperinsulinemia cause obesity or that treating either of these conditions reduces obesity. It should be pointed out that hyperamylinemia is only one of the metabolite alterations in obesity. Although Huang suggests that it could act as a causative mechanism, there is no indication that it is the only factor or even a primary factor responsible for inducing an obese state. As is clear from the attached articles, Pi-Sunyer, F.-X. *et al.*, "Therapeutic Controversy: Obesity - A Modern Day Epidemic," (1998), *Journal of Clinical Endocrinology and Metabolism*, 84(1):3-7 and Campfield, L. A. *et al.*, "Strategies and Potential Molecular Targets for Obesity Treatment," (1998), Science, 280:1383-7, the biochemical circuitry governing energy intake and expenditure and, therefore body weight and composition, are immensely complex. That the effects of the somatostatin compounds claimed in the present invention extend well beyond that of suppressing amylin production alone is evident in the lowering of plasma triglycerides in obese Zucker rats as described on pages 22 to 24 of the instant specification. The disclosed findings are neither taught nor suggested by either Dunmore or Huang. While it is readily admitted that Dunmore does teach that, by preventing hyperamylinemia, somatostatin agonists can be used to treat non-insulin dependent diabetes, however, it would, by no means, be apparent to a skilled artisan that a

treatment suitable for type II diabetes would also be generally useful in treating obesity. For example, sulfonylureas and metformin, which are currently used for treating type II diabetics, are not used to treat obesity. Applicants assert that there is not direct connection between hyperamylinemia and obesity and as such, it is submitted that it would not be obvious to one skilled in the art that somatostatin agonists would have any beneficial effect in the treatment of obesity, still less a somatostatin type-2 receptor agonist or a somatostatin type-5 agonist having a Ki of less than 2nM. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 4, 6, 8, 10, 11 and 32 are rejected under 35 U.S.C. 103 as being unpatentable over WO 96/35950 in the name of Dunmore *et al.* in view of Huang, H.-J., Suppl. Hypertension, (1992) 19(1):I101-9.

CONCLUSION

Applicants submit that the grounds for rejection asserted by the Examiner have been overcome, and that the claims, as now pending, define subject matter that is novel and nonobvious over the prior art. On this basis, it is submitted that allowance of the instant application is proper, and early favorable action is solicited.

Pursuant to 37 C.F.R. 1.136, Applicants hereby petition that the period for response to the pending office action be extended for three months to and including August 25, 2004.

Should Examiner Robinson deem any further action is required of the Applicants to place this application in a condition for issue, she is requested to telephone the Applicants' undersigned representative.

Respectfully submitted,

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